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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/657,570

09/08/2003

Nizal Chandrakumar

2927/1A/US
(6794-000085/D)

9862

7590

06/23/2005

Pharmacia Corporation
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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,570

Applicant(s)

CHANDRAKUMAR ET AL.

Examiner

Kevin E. Weddington

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Claims 27-35 are presented for examination.

Applicants' amendment filed March 18, 2005 has been received and entered.

Accordingly, the rejection made under 35 USC 103 as set forth in the previous Office action at pages 3-5 is hereby withdrawn because the cited reference, Fisher et al. (5,451,677) does not teach the applicants' preferred compounds, phenylcarbonylaminophenylsulfonylaminoethylcarbonyl core or phenylsulfonylaminophenylsulfonylaminoethylcarbonyl core.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 27 is again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S.

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Patent No. 6,677,308. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a method for treating diabetic retinopathy in a mammal with an effective $\alpha v\beta 3$ inhibiting amount of meta-substituted phenylene sulphonamides, and the patented application teaches a method for treating conditions mediated by the $\alpha v\beta 3$ integrin in a mammal with the same derivatives. Clearly, the patented application's broad method of treating conditions includes the present application's diabetic retinopathy since the patented application states in column 15, line 25, that 'diabetic retinopathy' is a condition mediated by $\alpha v\beta 3$ integrin.

The rejection made under obviousness-type double patenting is adhered to

Claim 27 is not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject

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matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

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The claimed invention relates to a method for treating diabetic retinopathy in a mammal in need of such treatment, wherein: the method comprising administering an effective α v β 3 inhibiting amount comprising from about 0.01 mg to about 1000 mg per kilogram of body weight of phenylcarbonylaminophenylsulfonlyaminoethylcarbonyl core or phenylsulfonylaminophenylsulfonylaminoethylcarbonyl core compounds disclosed in claim 27.

The relative skill of those in the art is generally that of a Ph.D. or M.D. The present invention is unpredictable unless experimentation is shown for the phenylcarbonylaminophenylsulfonlyaminoethylcarbonyl core or phenylsulfonylaminophenylsulfonylaminoethylcarbonyl core compounds of claim 27 to treat diabetic retinopathy.

The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples showing the instant phenylcarbonylaminophenylsulfonlyaminoethylcarbonyl core or phenylsulfonylaminophenylsulfonylaminoethylcarbonyl core compounds of claim 27 will treat diabetic retinopathy.

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The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the phenylcarbonylaminophenylsulfonylaminoethylcarbonyl core or phenylsulfonylaminophenylsulfonylaminoethylcarbonyl core compounds of claim 27 are effective in treating diabetic retinopathy. The level of experimentation needed to determine the other instant compounds would be able to treat diabetic retinopathy is undue. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 27-35 are not allowed.

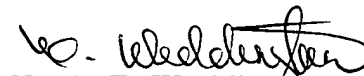
The reference cited on the enclosed PTO-892 is cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571) 272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
June 21, 2005